भारतीय मानक
Indian Standard

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चिकित्सीय वस्त्रादि — घाव प्रबंधन और शल्य चिकित्सा प्रक्रियाओं के संपीड़न के लिए परीक्षण पद्धतियां

Medical Textiles — Test Methods for Compresses for Wound Management and Surgical Procedures

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Technical Textiles for Medtech Applications Sectional Committee, TXD 36

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by Technical Textiles for Medtech Applications Sectional Committee had been approved by the Textile Division Council.

Compresses are used for cleansing skin or wounds, absorbing body exudates during surgical procedures. Generally, only physical and chemical tests will be necessary for routine quality control of compresses once biological test requirements have been fulfilled. If changes are made to the product, biological retesting may be necessary.

The composition of the Committee responsible for the formulation of this standard is given in Annex K.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

MEDICAL TEXTILES — TEST METHODS FOR COMPRESSES FOR WOUND MANAGEMENT AND SURGICAL PROCEDURES

1 SCOPE

This standard specifies test methods involved for the evaluation of materials used in compresses for medical use.

2 TERMS AND DEFINITIONS

For the purposes of this standard, the following term shall apply:

2.1 Compress — Material in any form or size that is used for one or more of the following purposes:

a) for cleaning skin or wounds;
b) for absorbing body exudates during surgical procedures;
c) for use with agents commonly used in wound management; and
d) to support organs, tissue, etc. during surgical procedures.

3 WORKMANSHIP AND FINISH

The product shall be free from toxic or harmful substances. The manufacture and preparation of the compresses shall be conducted under proper hygienic conditions.

4 TEST CONDITIONS

Condition the sample and carry out tests under the conditions given in Annex A.

5 PHYSICAL PROPERTIES

Test methods are given below for determination of physical properties of the compresses:

a) Liquid absorbency time, according to Annex B;
b) Liquid absorptive capacity, according to Annex C;
c) Liquid retention capacity, according to Annex D; and
d) Wet linting, according to Annex E.

6 CHEMICAL PROPERTIES

Test methods are given below for determination of chemical properties of the compresses:

a) Water soluble substances, according to Annex F;
b) Fluorescence, according to Annex G;
c) Acidity/alkalinity of aqueous extract, according to Annex H;
d) Non-polar soluble substances, according to Annex I; and
e) Surface active substances, according to Annex J.

ANNEX A

(*Clause* 4)

TEST METHODS FOR CONDITIONING

A-1 PRINCIPLE

The object of this procedure is to specify the conditioning atmosphere and the method of conditioning materials before and during testing.

A-2 CONDITIONING ATMOSPHERE

A-2.1 Temperature: (27 ± 2)°C.

A-2.2 Relative Humidity (65 ± 2) Percent R.H.

A-3 CONDITIONING

A-3.1 Place the test specimen in the conditioning atmosphere.

A.3.2 Weigh the test specimen at intervals of not less than 2 h.

A.3.3 Retain the test specimen in the conditioning atmosphere until two last weighing do not differ by more than 0.25 percent of the total mass of the test specimen.

ANNEX B

[*Clause* 5 (a)]

TEST METHOD FOR DETERMINATION OF LIQUID ABSORBENCY TIME

B-1 PRINCIPLE

This test method evaluates the time required for complete wetting of compresses loosely rolled into a cylindrical wire basket and dropped onto the surface of the liquid.

B-2 APPARATUS

B-2.1 Cylindrical Copper Wire Basket — 80 mm high and 50 mm in diameter, fabricated from wire of diameter 0.4 mm and having a mesh aperture of 15 to 20 mm. The basket shall weigh 2.4 to 3.0 g.

B-2.2 Container for Liquid

B-2.3 Stop Watch

B-3 PROCEDURE

B-3.1 Take five samples, each weigh (5 ± 0.2) g, from different places in the material being examined.

B-3.2 Condition the test specimens and carry out the test under conditions according to **Annex A**.

B-3.3 Pack loosely a test specimen in the basket and weigh the packed basket to the nearest 10 mg. Hold the basket with its long axis in the horizontal position and drop it from a height of about 10 mm into water contained in a beaker at least 12 cm in diameter and filled to a depth of 10 cm.

B-3.4 Measure with a stopwatch, the time taken by the basket to sink below the surface of the water.

B-3.5 Repeat the procedure on four further samples.

B-4 RESULTS

Calculate the average liquid absorbency time.

ANNEX C

[*Clause* 5 (b)]

TEST METHOD FOR DETERMINATION OF LIQUID ABSORPTIVE CAPACITY

C-1 PRINCIPLE

This test method evaluates the mass of the liquid absorbed per unit mass of the compresses, expressed as a percentage, after standard immersion time.

C-2 APPARATUS

C-2.1 Wire Gauze — Made from stainless steel, of size at least 120 mm * 120 mm.

C-2.2 Container with Test Liquid — To accommodate the wire gauze with the test specimen attached.

C-2.3 Weighing Glass with Cover.

C-2.4 Stop Watch

C-2.5 Clips

C-3 PROCEDURE

C-3.1 Cut 5 test specimens of size (100 ± 1) mm. If an individual piece weighs less than 1 g, make up the test specimen from two or more layers until the total mass is at least 1 g.

C-3.2 Condition the test specimens and carryout the test under conditions according to **Annex A.**

C-3.3 Weigh the test specimen (W_1).

C-3.4 Place the gauze with test specimen 20 mm below the surface of the liquid contained in suitable dish.

C-3.5 After 60 s remove gauze and test specimen from the test liquid.

C-3.6 Hang the gauze and test specimen freely to drain vertically for (120 ± 3) s.

C-3.7 Take the test specimen off the gauze and place it in a weighing glass. Determine the mass of the test specimen (W_2).

C-3.8 Repeat the procedure on four further samples.

C-4 CALCULATION OF RESULTS

Calculate the liquid absorptive capacity (L_A) as a percentage from the expression:

$$L_A = \frac{W_2 - W_1}{W_1} \times 100$$

ANNEX D

[*Clause* 5(c)]

TEST METHOD FOR DETERMINATION OF LIQUID RETENTION CAPACITY

D-1 PRINCIPLE

This test measures the liquid retention of the compresses by difference of mass before immersion of the compresses in water and after immersion, draining and compression.

D-2 APPARATUS

D-2.1 Stainless Steel Tank

D-2.2 Stainless Steel Tray

The tray has a perforated metal base which can be suspended in the stainless steel tank, permitting a moistened material aid upon its surface to drain freely through the perforations. The base is perforated with circular holes, 3 mm in diameter, evenly spaced, so that the centre of each hole is 5 mm from the centres of those adjoining it.

D-2.3 Metal Weight

Use a suitable non-corrodible material which exerts a pressure of 2 kN m^{-2} (20 gf cm^{-2}).

D-3 PROCEDURE

D-3.1 Weigh the material being examined and place it on the perforated metal tray with the surface intended for wound contact in direct contact with the perforated surface.

D-3.2 Immerse the tray and material in water at a temperature of 20°C for 10 s. Transfer the tray and material to the stainless steel tank and allow the contents to drain for 10 s.

D-3.3 Place the metal weight on the surface of the material such that a force of 2 kN m^{-2} is applied evenly over the surface of the sample, leave for 30 s and then remove it carefully.

D-3.4 Transfer the material immediately by means of a pair of tweezers to a tared dish, taking care not to lose any water in the process, weigh and calculate the equivalent water-retention capacity for an area of 100 cm^2 of the compresses.

D-3.5 Record the results of five determinations and calculate the average liquid retention capacity.

ANNEX E

[*Clause* 5(d)]

TEST METHOD FOR WET LINTING

E-1 PRINCIPLE

This test is used to determine the number of particles/ fibres lost from the compress.

Submerged in water, the compress is shaken for a period of time to wash off any loose fibres. The water is then filtered. The numbers of particles recovered from the water are a measure of the wet linting of the compress.

E-2 APPARATUS

E-2.1 Closed Container — Large enough to contain, and allow free movement of a compress.

E-2.2 Laboratory Shaker

E-2.3 Flat Screen Filter — Set up using a flat, coloured, 1 micrometer pore size, gridded filter.

E-2.4 Microscope, or Powerful Magnifying Glass

F-2.5 Forceps

E-3 PROCEDURE

E-3.1 Place a compress in the container, and fill the container with deionized water to a level high enough to cover the entire compress.

E-3.2 Shake the container on the laboratory shaker set at 300 Hz to 350 Hz for 10 min.

E-3.3 Remove the compress from the container using forceps, and drain it vertically without squeezing.

E-3.4 Filter the water through the gridded filter.

E-3.5 Rinse the flask twice using water. Filter this water. Dry the filter.

E-3.6 Using the microscope or magnifying glass, determine the number of particles recovered.

E-3.7 Repeat **E-3.1** to **E-3.6** at least three times.

E-4 RESULTS

Calculate and report the results and average of the tests, expressed as “recoverable particles per compress” indicating which counting procedure has been applied.

ANNEX F

[*Clause* 6(a)]

TEST METHODS FOR WATER SOLUBLE SUBSTANCES

F-1 Boil 7 g with 700 ml of water for 30 min, stirring frequently, and replace the water lost by evaporation.

F-2 Decant the liquid into a beaker, squeeze the residual liquid from the material carefully with a glass rod, mix the liquids and filter the extract whilst hot.

F-3 Evaporate 400 ml and dry the residue to constant weight at 100 to l05°C.

ANNEX G

[*Clause* 6(b)]

TEST METHOD FOR DETERMINATION OF FLUORESCENCE

G-1 PRINCIPLE

These test methods evaluate the fluorescence of compress by observing for fluorescence under ultra-violet light.

G-2 PROCEDURE

G-2.1 Examine the compress under an ultraviolet lamp having a maximum output at a wavelength of 365 nm. Record whether or not the material fluoresces. If the compress shows a general uniform fluorescence, subject it to the test described in **G-2.2**.

G-2.2 Examine approximately 25 ml of the cooled filtered extract prepared for the determination of water soluble substances (*see* Annex F) in a cylindrical glass tube under ultraviolet light of wavelength 365 nm and similarly examine a sample of the water used to prepare the extract. A higher level of fluorescence than that of the water used to prepare the extract indicates that fluorescent components have been leached out from the material.

G-3 TEST REPORT

For each test specimen examined, record whether it is within the stated specification for the product.

ANNEX H

[*Clause* 6(c)]

TEST METHOD FOR DETERMINATION OF ACIDITY OR ALKALINITY OF AQUEOUS EXTRACTS

H-1 PRINCIPLE

This test method determines the acidity or alkalinity of an aqueous extract of a compress by means of a *p*H meter.

H-2 PROCEDURE

H-2.1 Calibrate a *p*H meter using a solution of known *p*H according to the operating instructions provided by the manufacturer of the *p*H meter.

H-2.2 Boil 7 g of material in 700 ml of distilled water for 30 min ensuring any water lost is replaced.

H-2.3 Measure the *p*H of the extract, cooled to a temperature of (20 ± 2)°C, to the nearest 0.1 *p*H unit by means of the *p*H meter.

ANNEX I

[*Clause* 6(d)]

TEST METHOD FOR DETERMINATION OF SUBSTANCES SOLUBLE IN NON-POLAR SOLVENTS

I-1 PRINCIPLE

This test method determines the amount of substances soluble in non-polar solvents in materials by means of evaporating an extract to dryness and weighing the residue.

I-2 APPARATUS AND REAGENTS

I-2.1 Continuous Extraction Apparatus

I-2.2 Non-polar Solvent, such as, analytical reagent grade diethyl ether or another analytical reagent grade non-polar solvent of molecular weight not greater than 150, for example, methylene chloride.

I-3 PROCEDURE

I-3.1 In the continuous extraction apparatus, (see **I.2.1**) extract (5 ± 0.05) g of material with non-polar solvent (see **I.2.2**) for 4 h at the rate of at least four extractions per hour.

I-3.2 Evaporate the solvent extract and dry the residue to constant mass at (105 ± 3)°C.

I-3.3 Calculate the amount of substances soluble in non-polar solvents as a percentage of the original mass of the test specimen.

ANNEX J

[*Clause* 6(e)]

TEST METHOD FOR DETERMINATION OF SURFACE-ACTIVE SUBSTANCES

J-1 PRINCIPLE

This test method determines the presence of anionic, cationic, or non-ionic surface-active substances in an extract of the compress by means of qualitative chemical tests.

J-2 APPARATUS AND REAGENTS

J-2.1 Selection of Boro-silicate Laboratory Glassware.

J-2.2 Hydrochloric Acid, 0.5 mol/l.

J-2.3 Aqueous Solution of Methylene Blue, 1 g/l.

J-2.4 Chloroform of Analytical Reagent Grade.

J-2.5 Aqueous Solution of Sodium Carbonate, 1.0 mol/l.

J-2.6 Aqueous Solution of Bromophenol, 4 g/l.

-.2.7 Solution of Barium Chloride, 50 g in 1 l of Hydrochloric Acid (*see* H.2.2).

J-2.8 Aqueous Solution of Phospho-molybdic Acid, 50 g/l.

J-2.9 Laboratory *p*H Meter.

J-3 PROCEDURE

J-3.1 Extraction

In a 100 ml flask equipped with a water-cooled condenser (*see* **J-2.1**), boil 1 ± 0.01 g of material in 50 ± 0.5 ml of distilled or deionized water for a minimum of 90 min.

J-3.2 Determination of Surface Active Substances

J-3.2.1 Anionic Surface-active Substances

J-3.2.1.1 To 5 ± 0.05 ml of the extract add hydrochloric acid (*see* **J-2.2**) until *p*H 4 to *p*H 5 is reached as measured by the *p*H meter (*see* **J-2.9**). Add 2 or 3 drops of methylene blue solution (*see* **J-2.3**). Stir vigorously, then add 5 ± 0.05 ml of chloroform (*see* **J-2.4**) and stir again.

J-3.2.1.2 Allow the mixture to separate into two layers. Inspect the chloroform layer. A blue colouration indicates the presence of anionic surface-active agents.

J-3.2.2 Cationic Surface-active Substances

J-3.2.2.1 To 5 ± 0.05 ml of the extract add sodium carbonate solution (*see* **J-2.5**) until *p*H 9 is reached as measured by the *p*H meter (*see* **J-2.9**). Add 2 or 3 drops of bromophenol solution (*see* **J-2.6**). Stir vigorously, then add 5 ± 0.05 ml of chloroform and stir again.

J-3.2.2.2 Allow the mixture to separate into two layers. Inspect the chloroform layer. A blue colouration indicates the presence of cationic surface-active agents.

J-3.2.3 Non-ionic surface-active substances

J-3.2.3.1 To 5 ± 0.05 ml of the extract add 5 ± 0.05 ml of barium chloride solution (*see* **J-2.7**). Stir, and if precipitation occurs, filter.

J-3.2.3.2 To the filtrate add 1 ml of phospho-molybdic acid solution (*see* **J-2.8**) and boil. Inspect the solution. A yellow-greenish precipitation, which does not change when boiling, indicates the presence of non-ionic surface-active substances.

ANNEX K

(*Foreword*)

COMMITTEE COMPOSITION

Technical Textiles for Medtech Applications, TXD 36

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